UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

GOVERNMENT EMPLOYEES HEALTH ASSOCIATION, on behalf of itself and all others similarly situated,

Plaintiff,

v.

ACTELION PHARMACEUTICALS LTD., *et al.*,

Defendants.

[redacted]

HEARING REQUESTED

Civil Case No.: 18-cv-3560-GLR

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

Defendants' (collectively, "Actelion's") motion for summary judgment should be denied. This case concerns Actelion's overarching scheme to delay market entry of lower-priced generic versions of its best-selling drug, Tracleer. The scheme prevented generic companies from acquiring samples of Tracleer that they needed to develop competing products. By delaying lower-priced competition for years, Actelion preserved its monopoly and took hundreds of millions of dollars from patients and payers such as GEHA. Because reasonable jurors can find for GEHA, summary judgment must be denied. *Adnet, Inc. v. Soni*, 66 F.4th 510 (4th Cir. 2023).

Numerous disputes of material fact preclude summary judgment. They include: (1) did the Tracleer REMS require Actelion to erect the samples blockade? The record demonstrates no, *infra* § IV.B.1, Actelion disagrees; (2) was Actelion's reliance on the Tracleer REMS pretextual? The record demonstrates it was, *infra* § IV.B.2, Actelion disagrees; (3) If not pretextual, could Actelion have satisfied its REMS concerns through less restrictive means? The record demonstrates it could have, *infra* § IV.B.2, Actelion ignores this material factual issue; (4) Absent the anticompetitive conduct, when would generics have acquired samples? The record demonstrates as early as late 2008, *infra* § II.E, Actelion disagrees; (5) Absent the anticompetitive conduct, when would generic Tracleer have come to market? The record demonstrates no later than 2016, *infra* § IV.D, Actelion again disagrees.

Actelion tries two arguments for summary judgment, but each is meritless. First, Actelion seeks dismissal under "duty to deal" law. But the Fourth Circuit already ruled this is not a "duty to deal" case. *Mayor of Baltimore v. Actelion Pharms. Ltd.*, 995 F.3d 123, 132 (4th Cir. 2021) (reversing grant of Actelion's motion to dismiss). Rather, GEHA's claims stem from Actelion's overarching anticompetitive scheme, which includes refusals to sell Tracleer to generics, *and* anticompetitive downstream contracts that thwarted generic development. Actelion fails to argue

under the correct legal standard, because it cannot win under that standard. And even under "duty to deal" law, the record supports a finding of liability. As the District of New Jersey recognized in rejecting Actelion's previous attempt to seek judgment on the pleadings as to these arguments, the antitrust laws do not permit a brand drug company to put a chokehold on an essential input necessary for its competitors to bring lower-priced generic versions to market.

Second, Actelion claims that GEHA's experts selected the wrong date for when generic companies would have acquired Tracleer samples absent Actelion's misconduct. Actelion is wrong. As with its "refusal to deal" misstep, Actelion ignores that this case challenges not only direct refusals to sell to generics, but also anticompetitive downstream contracts that locked up the Tracleer supply at distributors and pharmacies. Absent that anticompetitive contracting, the generics would have obtained brand samples earlier from those distributors and pharmacies. This is what GEHA's experts opine based on their experience and the record evidence. At most, this is a factual dispute not fit for resolution on summary judgment.

Perhaps recognizing that its conduct is unlawful under the antitrust laws, Actelion seeks an escape-hatch by invoking the Risk Evaluation and Mitigation Strategies ("REMS") program for Tracleer. It claims that the Tracleer REMS both mandated and motivated its misconduct. Actelion is wrong on both counts. As Dr. Keith Webber, the former Acting Head of FDA's Office of Generic Drugs opines, *nothing in the Tracleer REMS required Actelion to erect the samples blockade*. Nor did the Tracleer REMS actually motivate Actelion. In truth, the evidence reveals that Actelion was motivated by one thing only: to prolong its monopoly profits by delaying competition. At most, Actelion's REMS argument presents a disputed factual question which GEHA must be allowed to present to a jury.

II. FACTUAL STATEMENT

A. Tracleer is an extremely expensive medication that treats a life-threatening disease.

In 2001, Actelion began marketing Tracleer (the brand name for bosentan) after acquiring rights to the drug from another company where it had been invented. Ex. 1, Actelion-Roche License Agreement. Tracleer was Actelion's only product for well over a decade and by far its largest profit driver, generating close to a billion dollars in annual revenue. Ex. 2, 9/20/2022 Dep. of Shal Jacobovitz ("Jacobovitz Tr.") at 35:4-7, 35:14-36:7. This success was possible in part because of the high prices Actelion demanded for Tracleer. In 2012, Actelion was charging over $75,000 *per patient*, *per year* for the drug. *See* Ex. 3, Product Price List. These patients used the drug to treat a life-threatening condition known as pulmonary arterial hypertension.

B. The Tracleer REMS

Tracleer is subject to a REMS that includes what is known as ETASU—Elements to Assure Safe Use. Like other REMS programs, the purpose of the Tracleer REMS was to educate those prescribing and dispensing the product, as well as the patients taking the product, of the risks and conditions for safe use. During the relevant time period, the Tracleer ETASU included the following: Tracleer will only be (1) "prescribed by healthcare professionals who are certified by Actelion under 505-1(f)(3)(A);" (2) "dispensed by pharmacies, practitioners, and health care settings (dispensers) that are specially certified by Actelion under 505-1(f)(3)(B);" and (3) "dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)."[1] These provisions were meant to achieve the goals of the Tracleer REMS, which were: (1) "To enable informed risk-benefit decisions for treating patients with Tracleer;" (2) "To minimize the risk of hepatoxicity [liver damage] in patients who are exposed to Tracleer;" (3)

[1] Ex. 4, 8/7/2009 FDA Tracleer REMS Approval Letter at -930–34.

"To minimize the risk of fetal exposures in [potentially pregnant] female patients who are exposed to Tracleer;" and (4) "To educate prescribers, patients, and pharmacies on the safe-use conditions for Tracleer."[2] Nothing in the Tracleer REMS imposed any restrictions on selling Tracleer to generic manufacturers. Rather, the Tracleer REMS established a framework for ensuring that prescribers and patients are informed and take appropriate steps to ensure the drug is safely used. As explained below, a different set of regulations, including Institutional Review Board oversight, governs and ensures safe use by generic manufacturers.

C. Brand Tracleer samples are required to develop lower-priced generic versions.

The patent on Tracleer was set to expire in November 2015, at which point lower-priced generics should have entered the market.[3] In order to file an application with the U.S. Food and Drug Administration ("FDA") to market a generic version of a brand drug, FDA requires generic manufacturers to demonstrate "bioequivalence" ("BE")—*i.e.*, that their generic product has the "same rate and extent of absorption into the bloodstream" as the brand name drug[4]—by conducting studies using the brand version of the drug as a comparator.[5]

Not surprisingly, BE testing is closely regulated by FDA. Pursuant to FDA regulation, 21 C.F.R. § 320.31(d)(2), BE studies, such as those for bosentan, must be overseen by an independent Institutional Review Board ("IRB") in accordance with FDA regulations at 21 C.F.R. § 56.[6] An IRB is a group that has been formally designated to review and monitor

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[2] *Id*. at -930.

[3] *See* Ex. 5, 12/22/2022 Expert Rep. of Todd Clark ("Clark Rep.") ¶¶ 80, 288.

[4] *Pediamed Pharms., Inc. v. Breckenridge Pharm., Inc.*, 419 F. Supp. 2d 715, 720 (D. Md. 2006) (quoting *Pfizer, Inc. v. Miles, Inc.*, 868 F. Supp. 437, 441 n.1 (D. Conn. 1994)).

[5] Ex. 6, 12/22/2022 Expert Rep. of Dr. Keith Webber ("Webber Rep.") ¶ 40.

[6] *See* Ex. 6, Webber Rep. ¶ 44.

biomedical research involving human subjects. *See id.* In accordance with FDA regulations, an IRB is responsible for approving, requiring modifications to, or disapproving research involving human subjects. *See id.* IRB oversight ensures, both in advance and by periodic review, that appropriate steps are taken to protect human subjects in research, including that pertinent aspects of any REMS are followed in bioequivalence testing. *See id.*

Normally, generic manufacturers purchase samples of the brand product for BE testing from a pharmacy or wholesaler.[7] They do not need to submit their BE protocols to FDA, or anyone else, before purchasing the samples.[8] Once samples are obtained, the generic first conducts *in vitro* dissolution testing, which involves *no human subjects*, to evaluate whether the generic drug dissolves in a way that is comparable to the brand drug.[9] After *in vitro* testing, the generic manufacturer proceeds to testing in human subjects, under the supervision of an IRB. *Id.* These tests generally entail administering a single dose of the drug to a relatively small number (usually fewer than 30) of healthy volunteer human subjects. *Id.*

D. Actelion imposes a samples blockade to prevent competition.

FDA provides guidance on how to design BE studies for particular drugs. It first did so for generic Tracleer (bosentan) tablets in 2010.[10] Knowing that generic competitors needed samples of brand Tracleer to develop competing products, Actelion executed an overarching scheme to put a stranglehold on that essential input to generic development.[11] At the outset,

[7] Ex. 7, 12/22/2022 Expert Rep. of Daisy Rivera-Muzzio ("Muzzio Rep.") ¶ 31.

[8] *Id.* ¶¶ 25–26, 30.

[9] Ex. 6, Webber Rep. ¶ 42.

[10] Ex. 6, Webber Rep. ¶ 43. FDA issued further guidance in 2012. *See* Ex. 49.

[11] Ex. 8, 10/25/2022 Dep. of Rahsaan Thompson ("Thompson Tr.") at 127:4-18 (Actelion knew generics needed brand samples).

Actelion contractually barred its wholesaler and every pharmacy that possessed the drug from selling it to generic manufacturers absent Actelion's authorization, which it never provided.[12] These contract provisions were not mandated by the Tracleer REMS. Ex. 6, Webber Rep. ¶¶ 13, 35. FDA never reviewed these contracts, nor approved them. *Id.* ¶ 35; Ex. 13 at 14.

Without Tracleer samples, the generics were hamstrung and could not develop products to compete with Actelion. For example, as of November 2009, the generic comapny Zydus had "repeatedly attempted to purchase Tracleer from wholesale distribution channels," but "could not obtain the necessary domestic samples."[13] The generic [redacted] tried to purchase samples to develop a competing product in mid-2011, but none of its many suppliers could obtain them.[14] The generic [redacted] suffered the same fate: [redacted]

Unable to purchase Tracleer through normal pharmacy and distributor channels, the generics were "out of options." [redacted] With nowhere else to turn, prospective competitors approached Actelion directly to purchase brand samples. The generics'

[12] *E.g.*, Ex. 9, Actelion-Walgreens Contract at -072 ([redacted]); Ex. 5, Clark Rep. ¶ 75; Ex. 2, Jacobovitz Tr. at 69:18-23; Ex. 10, 10/7/2022 Dep. of Kevin Plamondon ("Plamondon Tr.") at 178:25-196:10; Ex. 11, 10/1/2008 Actelion-ICS Contract at -813; Ex. 12 (wholesaler seeking Actelion approval to make sale of Tracleer).

[13] Ex. 14, Zydus Answer and Counterclaims ¶¶ 37–38.

[14] [redacted]

[15] [redacted]

[16] [redacted]

purchase requests offered to pay "market value" for the drug and specified they would "fully comply with FDA requirements."[17] Actelion ignored their requests.[18] When the generics finally received a response, Actelion claimed that the Tracleer REMS prevented it from selling the brand samples.[19] However, that claim—and the claim that an FDA letter was required before Actelion could sell samples—was both false and pretextual. In truth, Actelion retained the right in its pharmacy contracts to sell to whomever it pleased.[20] Actelion's true motivation was to delay generic competition. *See infra* § IV.B.2. For example, after the generic Apotex obtained the FDA letter Actelion had demanded, Actelion still stonewalled. It wrote: "Actelion's right to refuse to do business with Apotex is ***not*** premised on the existence of the Tracleer REMS."[21]

E. Without Actelion's misconduct, generic entry would have occurred earlier.

In late 2012, Actelion sued the generic manufacturers. It sought a declaration blessing the barriers it had erected.[22] The generics filed antitrust counterclaims, which the court allowed to proceed, denying Actelion's motion for judgment on the pleadings.[23] Facing potential antitrust liability for its tactics, Actelion finally relented and entered settlement agreements allowing the generics to purchase Tracleer. After years of delay, Actelion sold Tracleer to the generics Zydus, Actavis, and Roxane without requiring or receiving an FDA letter regarding their BE protocols,

[17] [redacted]

[18] Ex. 22, 4/12/2011 Ltr. From Apotex; Ex. 14, Zydus Counterclaims at 13–14 ("Actelion did not respond to [Zydus's] request, leaving [it] without any means of accessing Tracleer samples").

[19] *E.g.*, Ex. 23, 7/2/2012 Ltr. To Apotex; Ex. 24, 8/9/2012 Ltr. To Roxane.

[20] Ex. 2, Jacobovitz. Tr. at 68:11-17; Ex. 9, Actelion-Walgreens Contract § 2.1. This belies Actelion's emphatic (but wrong) declaration that "Actelion could distribute Tracleer ***only*** through certified specialty pharmacies to patients enrolled in the REMS program…" Br. 5.

[21] Ex. 25, 5/30/2013 Ltr. To Apotex (emphasis in original).

[22] Ex. 7, Muzzio Rep. ¶ 68.

[23] Ex. 26, 10/17/2013 Hrg. Tr., *Actelion Pharms. Ltd. et al. v. Apotex, Inc., et al.* at 116:19-117:8.

and without altering the REMS that had purportedly blocked the sales.[24]

Generics Who Eventually Purchased Samples Directly From Actelion[25]			
Generic Company	*Date of First Samples Purchase Attempt*	*Date of Eventual Samples Acquisition*	*Did Actelion Receive FDA Letter re: BE Protocols?*
[redacted]	November 2009	March 2014	No FDA Letter
	January 2011	June 2014	No FDA Letter
	January 2011[26]	November 2013	FDA Letter
	July 2011	May 2014	No FDA Letter
Generics Who Sought to Purchase Samples Only Through the Normal Channels[27]			
[redacted]	September 2008	December 2011	N/A
	August 2011	August 2012	N/A

As this chart demonstrates, the generic companies were delayed *for years* in developing lower-priced competing products. They planned to launch their products as soon as Actelion's patent expired in 2015.[28] But Actelion's scheme delayed their efforts. No generic came to market until 2019, over three years after the patent expired.[29] Actelion reaped the benefits: during that delay, Tracleer sales brought in hundreds of millions of dollars.[30] When generic

[24] *See, e.g.*, Ex. 27, Actelion-Roxane Supply and Settlement Agreement at -495–96 (requiring 45-day notice to FDA of sale but no FDA approval of BE protocols).

[25] [redacted] Ex. 5, Clark Rep. ¶ 285 n.423; Ex. 31, 6/6/2011 Actelion Ltr.; Ex. 32, [redacted]; Ex. 7, Muzzio Rep. ¶¶ 31 n.12, 63 n.26.

[26] Apotex appears to have been seeking to purchase samples even earlier from wholesalers, *see* Ex. 33, Apotex Answer and Counterclaims at -312 ¶ 39, although the earliest precise date in the record is [redacted]

[27] Mylan: Ex. 18, 3/12/2009 Mylan Email; Ex. 34, Mylan Bosentan Bioequivalence Summary Table; Par: Ex. 15, Par Tr. at 61:10-14, 87:23-89:2.

[28] *E.g.*, Ex. 35, 10/24/2022 Dep. of Actavis ("Actavis Tr.") at 58:1-16.

[29] Ex. 5, Clark Rep. ¶¶ 80, 135, 175, 189, 227.

[30] Ex. 36, Actelion Profit and Loss Statement.

competition finally arrived, prices plummeted.[31] The delay thus harmed patients and payers such as GEHA, who paid inflated monopoly prices for years longer than they should have.

III. STANDARD OF REVIEW

Summary judgment is inappropriate unless the Court, after considering the record as a whole and in the light most favorable to GEHA, finds there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *In re Zetia (Ezetimibe) Antitrust Litig.*, 655 F. Supp. 3d 406, 418 (E.D. Va. 2023). The burden is on Actelion to demonstrate that no issues of material fact exist for trial. *Id.* "A material fact is one that might affect the outcome of the suit under the governing law. A disputed fact presents a genuine issue if the evidence is such that a reasonable jury could return a verdict for the non-moving party." *Spriggs v. Diamond Auto Glass*, 242 F.3d 179, 183 (4th Cir. 2001) (citations omitted) (internal quotation marks omitted); *Adnet, Inc. v. Soni*, 66 F.4th 510, 521 (4th Cir. 2023) (reversing summary judgment). "In considering a motion for summary judgment, 'the court must draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.'" *In re Zetia (Ezetimibe) Antitrust Litig.*, 2022 WL 4355149, at *9 (E.D. Va. Sept. 2, 2022) (quoting *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000)), *R. & R. adopted*, 655 F. Supp. 3d 406 (E.D. Va. 2023). "[T]he judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).

IV. ARGUMENT

GEHA's claim is "analogous to what has been termed a pay-for-delay scheme," *Mayor of Baltimore v. Actelion Pharms. Ltd.*, 995 F.3d 123, 132 (4th Cir. 2021) (citing *FTC v. Actavis,*

[31] Ex. 37, 12/22/2022 Expert Rep. of Dr. Meredith Rosenthal ¶ 83 Fig. 7.

Inc., 570 U.S. 136 (2013)), and is thus governed by the rule of reason. *Actavis*, 570 U.S. at 158–59. Under the rule of reason, a plaintiff first demonstrates monopoly power and anticompetitive effects. *United States v. Microsoft Corp.*, 253 F.3d 34, 58–59 (D.C. Cir. 2001) (en banc). The burden then shifts to defendants, who may proffer a "procompetitive justification." *Id.* The factfinder then decides whether "the anticompetitive harm . . . outweighs the procompetitive benefit." *Id.*; *United States v. Brewbaker*, 87 F.4th 563, 580 n.13 (4th Cir. 2023); *Dickson v. Microsoft Corp.*, 309 F.3d 193, 207 n.16 (4th Cir. 2002). "The rule of reason inquiry is fact-intensive," *In re Am. Honda Motor Co., Inc. Dealerships Rels. Litig.*, 941 F. Supp. 528, 561 n.43 (D. Md. 1996), making summary judgment "inappropriate" where "questions exist [] about the validity and sufficiency of each claimed justification." *Eastman Kodak Co. v. Image Tech. Serv., Inc.*, 504 U.S. 451, 483 (1992).

A. Reasonable jurors will find that Actelion's conduct violated the antitrust laws.

Actelion's motion does not dispute that it possessed monopoly power.[32] And reasonable jurors will conclude that Actelion caused anticompetitive effects in the relevant market. The front line of Actelion's defense was its anticompetitive distributor and pharmacy contracts, which forbid those entities from selling Tracleer to generics absent Actelion's permission, which it never granted.[33] Generic development requires purchasing brand samples from wholesalers or pharmacies,[34] including for REMS drugs.[35] By forcing distributors and pharmacies to turn away

[32] Nor could it. GEHA's expert Dr. Martha Starr conducted a thorough econometric analysis which concluded that Actelion possessed monopoly power over Tracleer and its generic equivalents. *See* Ex. 38, Starr Expert Rep. ¶¶ 71, 131-32; Ex. 39, Starr Rebuttal ¶ 2.

[33] *See, e.g.*, Ex. 10, Plamondon Tr. at 180:22-23, 190:21-191:8 ("our legal team would drive the negotiation and documentation."); Ex. 2, Jacobovitz Tr. at 77:23-78:14, Ex. 11, 10/1/2008 ICS Contract; Ex. 9, Actelion-Walgreens Contract, at -072.

[34] Ex. 7, Muzzio Rep. ¶¶ 25–31.

generics, Actelion delayed the development and eventual launch of their competing products.[36] These contracts alone thus "foreclosed competition . . . in a substantial share of the affected market" and were independently unlawful. *Imaging Ctr., Inc. v. Western Maryland Health Sys., Inc.*, 158 F. App'x 413, 420 (4th Cir. 2005); *FTC v. Shkreli*, 581 F. Supp. 3d 579, 629–30, 633–36 (S.D.N.Y. 2022) (liability for "restrictions in its distribution contracts, limiting the types of customers who could buy [the brand drug]").[37]

When the generics eventually submitted their purchase requests directly to Actelion, it continued to delay by simply ignoring them.[38] They prodded Actelion to respond, but Actelion concocted a ruse to buy more time. It claimed in some cases that the REMS blocked such sales entirely, and in others demanded the generic companies obtain FDA letters—an imagined "regulatory" bar. *Infra* § IV.B.2. As Actelion's counsel ultimately confirmed, however, the company's actions were "***not*** premised on the existence of the Tracleer REMS." Ex. 25. Through its pretextual stonewalling, Actelion "halted" the generics for years.[39] The generics testified that [redacted] and thus delays in market

[35] Ex. 40, 8/9/2023 Dep. of Daisy Rivera-Muzzio at 42:16-43:18; Ex. 41, 9/9/2022 Dep. of Karen Walker at 90:4-91:3.

[36] S[redacted]

[37] *See also Dinosaur Fin. Grp. LLC v. S&P Glob., Inc.*, 2023 WL 4562031, at *10–15 (S.D.N.Y. July 14, 2023); *In re Zetia (Ezetimibe) Antitrust Litig.*, 2019 WL 1397228, at *18 (E.D. Va. Feb. 6, 2019); *Cloverleaf Enter., Inc. v. Maryland Thoroughbred, Horsemen's Ass'n, Inc.*, 730 F. Supp. 2d 451, 465 (D. Md. 2010).

[38] *E.g.*, Ex. 14, Zydus Counterclaims ¶ 9.

[39] Ex. 45, 10/12/2012 Presentation at slide 15 [redacted].

entry.[40] Relying on this and other evidence, GEHA's expert Todd Clark opines that generic Tracleer products would have been available *years earlier* had Actelion not interfered with their development.[41] Reasonable jurors could thus conclude that Actelion willfully maintained its monopoly in violation of the antitrust laws. *See, e.g.*, *Zetia*, 655 F. Supp. 3d at 435.

Repeatedly, Actelion claims that the only "challenged conduct" is "Actelion's initial refusal to provide samples when requested." Defs.' Summ. J. Br. ("Br.") 1, 16, 26–27, 30. This is false.[42] GEHA challenges Actelion's overarching anticompetitive scheme to hinder competition. The scheme includes not only the refusal to sell Tracleer samples directly, but also the exclusionary contracts, the ignoring of purchase requests, and the leading generic companies on a pretextual goose chase to satisfy an invented regulatory bar—all of which is independently unlawful. Actelion's narrow view ignores that "the character and effect of a conspiracy are not to be judged by dismembering it and viewing its separate parts, but only by looking at it as a whole." *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962); *In re Suboxone Antitrust Litig.*, 622 F. Supp. 3d 22, 60 (E.D. Pa. 2022) ("Alleged antitrust conduct must be scrutinized as a whole…" (citing *Cont'l Ore Co.*, 370 U.S. at 699)). The record as a whole is more than sufficient for reasonable jurors to find Actelion liable for monopolization.

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[40] [redacted]

[41] Ex 5, Clark Rep. ¶¶ 16, 287–89.

[42] It also misleadingly suggests Actelion was asked to "provide" samples *gratis*. In fact, Actelion (and the distributors and pharmacies it tied up) were asked to *sell* samples, at profitable prices.

B. Actelion's claimed "legitimate business reason" is neither legitimate, nor the actual reason for Actelion's anticompetitive conduct.

Under the rule of reason, after the plaintiff proves its *prima facie* case, the defendant may proffer "a procompetitive justification—a nonpretextual claim that its conduct is indeed a form of competition on the merits . . . ." *Microsoft*, 253 F.3d at 59; *see also Viamedia, Inc. v. Comcast Corp.*, 951 F.3d 429, 489 (7th Cir. 2020). Contrary to Actelion's claim, Br. 15–16, raising justifications is a defendant's burden; it is not the plaintiff's burden to show an absence of justification.[43] In any event, the evidence here shows that there was no legitimate business justification for Actelion's challenged conduct, "making judgment inappropriate." *Eastman Kodak* 504 U.S. at 483. *First*, the Tracleer REMS did *not* require Actelion to erect the samples blockade. Substantial record evidence supports this conclusion, including the expert opinion of Dr. Keith Webber, a former FDA official who led FDA's Office of Generic Drugs, who opines that nothing in the Tracleer REMS required Actelion to erect the samples blockade. Ex. 6, Webber Rep. ¶¶ 13–14. Defendants have not moved to exclude Dr. Webber's opinion. *Second*, justifications cannot be pretextual. But Actelion's true motive—as documented by substantial evidence—was not to comply with the REMS, but instead to delay competition. *Third*, even a non-pretextual justification would not warrant summary judgment. It would merely trigger rule-of-reason balancing, which is a task for the jury. *Dickson*, 309 F.3d at 207 n.16.

[43] Actelion cites two district-court cases, Br. 15–16, but Supreme Court and Fourth Circuit law is clear that "the burden shifts to the defendant to proffer a procompetitive justification for its conduct." *Dickson*, 309 F.3d at 207 n.16; *Aspen*, 472 U.S. at 608 (defendant "did not persuade the jury that its conduct was justified"); *id.* (noting "[the defendant's] failure to offer any efficiency justification"). Of course, even if the burden were GEHA's, reasonable jurors can find that Tracleer REMS was *not* a legitimate business justification. *Infra* § IV.B.

1. The Tracleer REMS did not require Actelion to erect the samples blockade.

Reasonable jurors will conclude that, as detailed in Dr. Webber's opinion, the Tracleer REMS did not require Actelion to erect the samples blockade and is therefore not a legitimate justification.[44] Actelion points to nothing in the Tracleer REMS that governs or prevents the sale of Tracleer to generic manufacturers. Nothing does. That is because the Tracleer REMS sets forth the conditions for prescribers, pharmacies, and patients to prescribe, dispense,[45] and use Tracleer safely. Nothing in the text of the REMS even mentions (let alone prevents) selling Tracleer to generic manufacturers. Put simply, the REMS does not govern inter-company sales. Indeed, FDA issued a Guidance document in 2010 setting forth how it expected generics to conduct BE testing for bosentan.[46] This shows that FDA intended generic drug developers to have access to samples of Tracleer. There would be no reason to issue guidance for testing if it were FDA's position that Tracleer could not be sold to generic drug developers. The Guidance for bosentan made clear that pertinent aspects of the REMS could and would be followed in conducting BE testing. Indeed, the generics told Actelion when submitting purchase requests that they would implement those pertinent aspects of the REMS.[47] To the extent Actelion disputes that these commitments constituted "adequate assurances," that is yet another dispute of fact.

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[44] Notably, Actelion wholly ignores Dr. Webber's opinion regarding the Tracleer REMS. That head-in-the-sand approach is inconsistent with a moving party's burden on summary judgment.

[45] "Dispensing" has a longstanding specific meaning under FDA regulations: "delivering a prescription drug product to a patient or an agent of the patient," 21 C.F.R. § 208.3(b), which confirms what is obvious from the plain text of the REMS: the Tracleer REMS does not impose any restrictions on inter-company sales.

[46] *See* Ex. 48, 9/2010 FDA Draft Guidance on Bosentan; Ex. 49, 3/2012 FDA Draft Guidance.

[47] [redacted] Likewise, when Actelion eventually sold Tracleer samples, it did not modify the REMS—proving the REMS was never a barrier, and the so-called "assurances" Actelion obtained were only what the generics

FDA's issuance of the Tracleer BE Guidance was consistent with the general regulatory backdrop, which also refutes Actelion's position. Bioequivalence testing is governed by specific FDA regulations that exist independent of any REMS program. For example, BE testing must be overseen by an independent IRB which itself is governed by FDA regulations.[48] It is the IRB—not Actelion—which has the authority and mandate to supervise research involving human subjects. *Id*. It is the IRB—not Actelion—which ensures that appropriate steps are taken to protect humans participating in research, including that pertinent aspects of any REMS are followed. *Id*. Generic manufacturers must submit their testing protocols to the IRB before conducting any human testing, and those seeking to conduct BE testing with Tracleer would have done so—and did in fact do so—at the appropriate time in their development process.[49]

The risk that brand companies would try to misuse the REMS to block generics was a chief concern of Congress and FDA—as they made clear early and often. Providing access to lower-cost generic drugs is a high public health priority and was a central purpose of the 1984 Hatch-Waxman Act. *Caraco Pharm. Lab'ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405, 407–08 (2012).[50] Accordingly in 2007, Congress included in the statute authorizing REMS an express prohibition against using REMS "to block or delay" generic drug applications.[51] In a July 2010

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had always committed to doing, *i.e.*, follow the pertinent aspects of the REMS. *See* Ex. 6, Webber Rep. ¶ 44; *see* Ex. 8, Thompson Tr. at 117:23-118:21, 120:15-124:22.

[48] *See* Ex. 6, Webber Rep. ¶ 44 (citing 21 C.F.R. §§ 320.31(d)(2), 56).

[49] Ex. 50, Clark Rebuttal ¶ 48. Moreover, Actelion's misconduct delayed *all* aspects of generic development—including *in vitro* dissolution testing, which does not involve human subjects at all. Ex. 6, Webber Rep. ¶ 41.

[50] The public health benefits and cost savings of wide access to generic drugs are well-documented. *See* Ex. 5, Clark Rep. ¶ 22.

[51] 21 U.S.C. § 355-1(f)(8). FDA expressly warned brand companies not to violate this section in letters approving new drugs as early as 2010, and sent one such warning to Actelion in 2012. *See*

meeting attended by Actelion, FDA stated it was "trying to make sure that REMS are not used to block or delay generic competition," and explained that none of the "REMS with restricted distribution programs" would do so.[52] In 2014, an FDA Director lamented that drug companies were "abusing the system" which was "designed to try to ensure the safe use of the drug" but was being turned into "an evergreening system for avoiding generic competition."[53]

Contrary to Actelion's insinuations, FDA's 2014 Guidance on how generic manufacturers could obtain a letter from FDA to facilitate acquiring samples of REMS drugs[54] was not a clarification of FDA's policy, which was well known. The Guidance was FDA's attempt to curb this ongoing abuse of REMS by brand drug companies.[55] The agency made this clear in the Guidance itself: *"Requesting or obtaining such a letter from FDA is not a legal requirement."*[56] Actelion's own expert agrees this was not a legal requirement.[57] Indeed, FDA accepted and approved bosentan ANDAs from many generics who never received such a letter.

Because initial efforts to stop REMS abuse were unsuccessful, further legislation became necessary. Lawmakers expressed their frustration with REMS abuse during 2016 Congressional hearings related to the CREATES Act. The bill was not enacted until 2019, but the REMS abuse

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Ex. 51, 8/4/2023 Rebuttal Rep. of Keith Webber ("Webber Rebuttal") ¶ 9 n.10; https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/021290Orig1s020ltr.pdf.

[52] Ex. 51, Webber Rebuttal ¶ 10 (citing FDA Public Meeting 270, https://perma.cc/V22K-99B7).

[53] *Id.* ¶ 13(a) (citing Derick Gingery, *REMS That Block Generics Are 'Major' Problem for FDA, Jenkins Says*, The Pink Sheet (Jan. 8, 2015)).

[54] Ex. 52, FDA Guidance, "How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols contain Safety Protections Comparable to Applicable REMS for RLD."

[55] *Id.* at -844 ("FDA is aware of instances in which [a brand] has refused to sell drug product to a prospective ANDA applicant seeking to conduct the testing needed to obtain approval…").

[56] *Id*.

[57] Ex. 53, 7/25/2023 Dep. of Martin Shimer at 42:8-9.

had been longstanding. For example, during a 2016 Senate hearing, Senator Grassley stated that the proposed CREATES Act was intended to "address the specific anticompetitive abuse and manipulation of the FDA safety regulations we had heard about from the FTC." He noted the CREATES Act targets the exact type of abuse that Actelion was engaging in: refusing to sell samples.[58] The FTC Chairwoman testified that "The FTC continues to be very concerned about potential abuses by branded pharmaceutical companies of REMS or other closed distribution systems to impede generic competition," and "this conduct undermines the careful balance Congress struck in the Hatch-Waxman Act . . . "[59]

In 2017, FDA reaffirmed its commitment to combatting brands' "gaming" tactics to delay approval of generic drugs, including withholding brand products for BE testing. FDA Commissioner Gottlieb recognized that "branded companies may be using regulatory strategies or commercial techniques to deliberately try to block a generic company from getting access to testing samples."[60] FDA published the RLD Access Inquiries List, naming brand companies who had denied access to samples of their drugs for generic development. Actelion was a top offender, having thwarted generic development of multiple products, including Tracleer.[61]

In sum, the Tracleer REMS neither required nor justified Actelion's misconduct. At the absolute minimum, the parties have a serious dispute of material fact as to how the Tracleer REMS applied in this situation. Summary judgment is therefore inappropriate.

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[58] Ex. 51, Webber Rebuttal ¶ 13(c) (citing Senator Grassley testimony).

[59] *Id.* ¶ 13(d); *see also id.* ¶ 13(b) (Senator Collins: "certain brand name companies . . . made it difficult for generic companies to get sufficient amount of the drug in order to conduct the bioequivalence studies that FDA requires.").

[60] Ex. 54, Scott Gottlieb, "FDA Working to Lift Barriers to Generic Drug Competition" at 2.

[61] Ex. 55, FDA Reference Listed Drug (RLD) Access Inquiries.

2. The REMS was a pretext; Actelion's actual, and only, motivation was delaying generic competition.

Reasonable jurors can find that Actelion's REMS excuse was pretextual, which is an independent reason to deny summary judgment. *Microsoft*, 253 F.3d at 59; *Mylan Pharms. v. Celgene Corp.*, 2018 WL 11299447, at *15 (D.N.J. Oct. 3, 2018).[62] Despite claiming a purported concern about REMS compliance, Actelion cites *not a single internal document* showing that it actually held the concerns it professes. There are none. Conversely, there is ample evidence that Actelion's true motivation was unlawful: to delay competition and keep its monopoly profits.

Internal Actelion documents provide substantial evidence of pretext. Years before its U.S. patent was set to expire, Actelion was planning "Tracleer Defense Options" throughout its global operations. The company's focus was on using "regulatory requirements" such as REMS to hinder generic competition.[63] For example, in planning for generic competition in Canada, Actelion sought out "regulatory hurdles that could delay approval" by "drawing on Tracleer experience in US." *Id*. at slide 5. In fact, Actelion wanted to explore a "REMS-alike program" for Canada so that it could be used for the same blocking effect that Actelion was using it for in the U.S.[64] As part of its global strategy for thwarting generic competition, Actelion identified "closed distribution regulations" as " serious entry hurdles" that could block generics.[65] Actelion resolved to "[c]hallenge any [generic] entry," including with "limited access to finished product to perform [bioequivalence] studies[.]" *Id*. at 674. Actelion's use of the REMS to block generics

[62] *Microbix Biosystems, Inc. v. Biowhittaker, Inc.*, 172 F. Supp. 2d 680, 693 (D. Md. 2000) (summary judgment is inappropriate where evidence supports "a finding that the Defendants' proffered 'legitimate business purposes' are pretextual.").

[63] *See, e.g.*, Ex. 56, Actelion Tracleer Early-LoE Project Presentation at slide 6; *see also id*. at slide 17 (listing "Regulatory requirements" to "maintain[] assets despite [] loss of exclusivity").

[64] Ex. 57, 4/22/2010 Actelion eLOE Canada Presentation at slides 6–7, 10, 18, 20.

[65] Ex. 58, Actelion Tracleer or Stayveer Strategic Direction Presentation at -673.

was one of the company's proudest achievements: in 2016 a member of Actelion U.K. asked U.S. employees how the U.K. entity might "tighten up the controlled distribution requirements to make it more of a barrier," noting that Actelion U.S. had "done an excellent job on this."[66]

The intention within Actelion to thwart generic competition rose to the highest levels. Bill Fairey, Actelion's U.S. President during much of the relevant time period, devised a plan in his prior role at the company's Asian affiliate to "erect barriers to possible generic entrants."[67] In his deposition, Mr. Fairey confirmed Actelion's views regarding competition: "when a company has invested and brought a product to market and that product is subject to generic competition, that's not a fortunate situation."[68] So too with Shalom Jacobovitz, Actelion's U.S. President before Mr. Fairey: a 2010 document states that he would be notified of any samples request "from a pharmaceutical competitor that does not benefit Actelion."[69] Moreover, while Actelion was preventing prospective competitors from acquiring samples under the guise of the REMS, it was simultaneously providing copious quantities of the product to academic researchers. But Actelion *did not* require those academic researchers to uniformly comply with the REMS.[70] In sum, the record is full of internal, contemporaneous documents showing that Actelion intended to stymie generic competition and viewed the REMS as its sharpest weapon.

When generic companies finally satisfied Actelion's artificial demands for FDA letters, the company's counsel revealed the pretext. He wrote: "Actelion's right to refuse to do business with Apotex is ***not*** premised on the existence of the Tracleer REMS." Ex. 25 (emphasis in

[66] Ex. 59, 8/12/2016 Internal Actelion Email at -053.

[67] Ex. 60, 6/1/2010 Email from Bill Fairey at -263.

[68] Ex. 61, 10/12/2022 Dep. of Bill Fairey at 209:12–25.

[69] Ex. 62, Actelion Protocol Rev. Comm. Meeting Minutes at -833.

[70] *See* Ex. 63, 9/27/2022 Dep. of Ryan Harris ("Harris Tr.") at 87:22-88:8.

original). That explains why Actelion also prevented competitors from purchasing samples of other drugs in its portfolio, *which were not covered by a REMS at all*.[71] The only reason that Actelion erected the samples blockade was to delay competition and enrich itself. The REMS was a convenient excuse for Actelion; it was never the company's true motivation. This conclusion is not merely GEHA's position: it was clear to the generics who suffered the delay, as they testified in this case and stated in their court-authorized antitrust claims against Actelion.[72]

Actelion principally relies on *Mylan* and *Natco*, but neither supports its argument.[73] Most significantly, GEHA has adduced overwhelming evidence of pretext not present in those cases. *See generally supra.* The plaintiff in *Natco* did not even allege pretext. In *Mylan*, the plaintiff merely "implie[d]" that the defendant had supplied the drug to academic researchers outside the REMS program; but in fact, "every single patient" had been enrolled in the RiskMAP. 2018 WL 11299447, at *14. By contrast, GEHA deposed an academic researcher who testified that Actelion provided Tracleer *without* requiring enrollment in the Tracleer REMS. Ex. 63, Harris Tr. at 87:22-88:8. *Mylan* is also inapt because the brand there required generics to obtain FDA letters; here, Actelion sold Tracleer to *multiple* generics without FDA letters. *Supra* II.E. Moreover, *Mylan* only involved refusals to sell—not anticompetitive contracts.[74]

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[71] *See* Ex. 64, Roxane's Answer and Counterclaims at -365–66 (detailing Actelion's blocking generic from purchasing samples of its drug Zavesca, which did *not* have a REMS).

[72] *See, e.g.*, Ex. 35, Actavis Tr. at 89:24-90: 20 ("Actelion's conduct is entirely pretextual and [its] sole motivation is to delay the entry of legitimate generic competition"); Ex. 26, 10/17/2013 Hrg. Tr. at 116:19-117:8 (the generics "offer to prove to the Court that the existence of safety concerns is really just a beard [] to mask the true motivation . . . to extract monopolistic profits").

[73] *Mylan Pharms, Inc. v. Celgene Corp.*, 2018 WL 11299447 (D.N.J. Oct. 3, 2018); *Natco Pharma Ltd. v. Gilead Sci., Inc.*, 2015 WL 5718398 (D. Minn. Sept. 29, 2015).

[74] *Natco* named one pharmacy as a defendant but did not involve anticompetitive clauses injected into every downstream contract. Moreover, *Natco* was a 12(b)(6) decision. It means little here, as the misconduct was already held to state a claim. *Infra* § IV.C.

Notably, *Mylan* denied summary judgment in part, so that the jury could evaluate whether the brand had "purposefully developed iterative requests for which no reasonable end could be reached." 2018 WL 11299447, at *18–19. That is exactly what Actelion did here. For example, Actelion spent years telling Apotex to obtain FDA review of its BE protocols, only to *continue* refusing to sell after Apotex received an FDA letter.[75] In Roxane's case, Actelion invoked the REMS in demanding that Roxane answer a series of irrelevant questions—knowing that, as with Apotex, it would not sell samples regardless of how Roxane answered.[76] Even after settling the litigation, Actelion continued to stonewall other generics; for example, the generic company Sun even obtained an FDA letter blessing its BE protocols, but Actelion still delayed:

> Since providing this letter, we have reached out to you *five times* in the past two weeks asking Actelion to comply with its contractual obligations. The only response, so far, is that you "don't have much to report." We find Actelion's failure to respond troubling. [77]

Ultimately, Actelion always planned to pretextually use "regulatory hurdles" (*i.e.*, REMS) to delay generics. *Mylan* recognized that REMS excuses can be pretextual, and thus on this record that court would have denied summary judgment—just as this Court should. *Id.* at *15 (citing *In re Thalomid and Revlimid Antitrust Litig.*, 2015 WL 9589217 (D.N.J. Oct. 29, 2015)).[78]

Lastly, even if the Tracleer REMS were a legitimate justification (it is not), that would merely trigger rule-of-reason step three analysis, where the jury balances the claimed justification against the anticompetitive harm, and assesses whether the justification could have been achieved through less-anticompetitive means. *Dickson*, 309 F.3d at 207 n.16. Here, such

[75] *Supra* § II.D; *see* Ex. 6, Webber Rep. ¶¶ 60 (Actelion ignoring requests for over a year).

[76] Ex. 24, 8/9/2012 Ltr. to Roxane.

[77] Ex. 65, 9/19/2015 Email from Sun at -010.

[78] Further, *Mylan* and *Natco* evaluated different REMS programs for different drugs. This Court must consider the Tracleer REMS, which does not justify Actelion's misconduct. The programs' requirements differ. *E.g.*, *Natco*, 2015 WL 5718398, at *7.

means existed.[79] Because reasonable jurors can conclude the Tracleer REMS did not mandate the misconduct and was pretextual, it fails to support summary judgment.

C. Actelion's fallback duty-to-deal argument does not excuse its misconduct.

Actelion also argues that even without the REMS, the only conclusion a reasonable juror could reach is to exonerate under "duty to deal" law. Br. 22–25. Actelion is wrong. Initially, this is not a duty-to-deal case. The Fourth Circuit already held that to "characterize[] the plaintiffs' complaint as a refusal-to-deal case" is a "misunderstanding of the nature of the causes of action . . . and of the nature of the injury alleged." *Id.* at 129. Rather, this case is "more closely analogous to what has been termed a pay-for-delay scheme" and thus governed by the rule of reason. *Actelion*, 995 F.3d at 132 (citing *Actavis*, 570 U.S. at 136).[80] The Fourth Circuit decision rejecting Actelion's narrow view of the liability theory is law of the case. *Fusaro v. Howard*, 19 F.4th 357, 367 (4th Cir. 2021). This Court should reject Actelion's effort to revive its duty-to-deal arguments here. In fact, Actelion already lost these exact legal arguments when it sued the generics. Actelion sought judgment on the pleadings and filed a brief mirroring that which it filed here. *See* Ex. 66 at 11–18. The court denied the motion.[81] The arguments remain meritless.

1. The duty-to-deal cases support antitrust liability.

Actelion's conduct violates duty to deal law. The right to sell to some customers but not others "is not unfettered." *Abcor Corp. v. AM Int'l, Inc.*, 916 F.2d 924, 929 (4th Cir. 1990). Refusals to deal are unlawful when "conceived in monopolistic purpose or market control."

[79] For example, Actelion could have given FDA 45 days' notice of the samples sale, as it did in settling the generics' antitrust claims. Ex. 27 at -495-96. This would have avoided years of delay.

[80] Actelion's summary judgment brief never mentions the rule of reason. That failure to "identify . . . the proper standard by which the Court should review" the motion is an independent basis to deny it. *Prusin v. Canton's Pearls, LLC*, 2018 WL 620473, at *3 (D. Md. Jan. 30, 2018).

[81] Actelion again argued this in unsuccessfully moving to dismiss here. *See* ECF 39-1 at 25–26.

Times-Picayune Publ'g Co. v. United States, 345 U.S. 594, 625 (1953). Thus, a monopolist may not discriminate against its competitors, *Otter Tail Power Co. v. United States*, 410 U.S. 366, 369-72 (1973), or sacrifice short-term profits to extract anticompetitive gains. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 601 (1985) (affirming liability after jury trial).

The recent case of *FTC v. Shkreli* is instructive.[82] Here and in *Shkreli*, the defendant "prevented generic drug companies from getting access to the quantity of [brand drug] they needed to conduct [bioequivalence] testing." *Id.* In both cases, the defendant not only refused direct purchase requests but also entered "restrictive distribution contracts," which "delayed the entry of generic competition for at least eighteen months." *Id.* at 590, 629. The court in *Shkreli* held a bench trial and found the defendant liable for monopolization. *Id.* at 636–37, 643. The court not only ordered disgorgement, but also entered an order "*banning [the defendant] for life from participating in the pharmaceutical industry in any capacity*." *Id.* at 643. The Second Circuit recently affirmed that lifetime ban. 2024 WL 1026010 (2d Cir. Jan. 23, 2024). As *Shkreli* and other courts have held, constricting access to brand samples violates antitrust law.[83]

The rule against samples blockades is not only sensible, but necessary given the regulatory background. *Ratino v. Med. Serv. of D.C.*, 718 F.2d 1260, 1272 (4th Cir. 1983) ("The district court should consider [] the facts peculiar to the health care industry…"). Congress enacted Hatch-Waxman "to speed the introduction of low-cost generic drugs to market." *Caraco*, 566 U.S. at 405. The Act requires generic companies to obtain brand samples to develop competing products. If a brand company could simply shut off access to that input, it would

[82] 581 F. Supp. 3d 579 (S.D.N.Y. 2022), *aff'd* 2024 WL 1026010 (2d Cir. Jan. 23, 2024).

[83] *E.g.*, *Thalomid*, 2015 WL 9589217, at *2; Ex. 26 at 116-117; *Lannett Co. v. Celgene Corp.*, No. 8-cv-3920, ECF 42 (E.D. Pa. Mar. 31, 2011). *Shkreli* did not involve a REMS product, but Actelion's duty-to-deal arguments are "[i]ndependent of the… Tracleer REMS." Br. 22.

short-circuit the entire Congressional scheme. Thus, Hatch-Waxman presupposes an obligation to not meddle in samples acquisition efforts. The REMS statute is explicit: it forbids using REMS "to block or delay approval of a [generic drug]." 21 USC 355-1(8). Reasonable jurors can find Actelion liable for violating that anti-meddling obligation through its overarching scheme to "sacrifice short-run benefits"—*see, e.g.*, Ex. 15, [redacted] ([redacted] would pay $150,000 for samples); Ex. 35, [redacted] ($221,850 [redacted])—"in exchange for a perceived long-run impact on its smaller rival." *Aspen*, 472 U.S. at 611–12.[84]

2. The essential facilities doctrine independently supports liability.

Where a monopolist uses its resources as a strategic bottleneck to exclude competition without a legitimate business justification, it violates the antitrust laws. *Adv. Health-Care Servs., Inc. v. Radford Cmty. Hosp.*, 910 F.2d 139, 150-51 (4th Cir. 1990). "Essential facilities" have been found to include stadium leases, railroad tracks, telephone lines, and brand drug samples.[85] While Actelion denigrates the doctrine as "so-called," Br. 24, in truth it "has a long and respected history as part of U.S. antitrust law."[86] The elements are: (1) the monopolist controls an essential resource; (2) the competitor cannot practically duplicate it; (3) the monopolist withholds the resource; and (4) the monopolist could feasibly provide access.[87]

Reasonable jurors could find each element of the doctrine satisfied based on this record. Brand Tracleer samples were a necessary resource for generics to develop competing products.

[84] *See also Viamedia*, 951 F.3d at 459 (allowing claim where defendant sacrificed profits).

[85] *Laurel Sand & Gravel v. CSX Transp., Inc.*, 924 F.2d 539 (4th Cir. 1991) (railroads); *Fishman v. Wirtz*, 807 F.2d 520 (7th Cir. 1986) (stadiums); *Revlimid*, 2015 WL 9589217 (drug samples); *Ohio Bell Tel. Co. v. CoreComm Newco*, 214 F.Supp.2d 819 (N.D. Ohio 2002) (telephone lines).

[86] Pitofsky et al., *The Essential Facilities Doctrine Under U.S. Antitrust Law*, 70 Antitrust L.J. 443, 445 (2002).

[87] *Radford*, 910 F.2d at 150. It is not cabined to conduct harming competition "in a different market." Br. 24. That is "monopoly leveraging," a distinct claim. *Radford*, 910 F.2d at 150.

Those companies could not duplicate the brand tablets themselves; FDA ordered them to use official U.S. Tracleer tablets—even Canadian samples would not suffice. Ex. 5, Clark Rep. ¶ 92. Actelion restricted their access to samples through its overarching scheme of exclusionary contracts, invented regulatory demands, and refusals to sell. And Actelion could have feasibly sold to generics. It ultimately did so (after years of delay) and received sizable payments in turn.

3. Actelion's counterarguments fail.

Actelion raises a few factual arguments, but none moves the needle. *First*, it claims that [redacted] obtaining samples excuses Actelion's misconduct. Br. 23, 25. But [redacted] were delayed *for years* by the anticompetitive contracts. *Supra* § II.E. That two victims eventually overcome the wrongdoing "does not condone the antitrust tactics which [Actelion] sought to impose." *Otter Tail*, 410 U.S. at 381.[88] Nor does it erase the experiences of the other generics, who were completely blocked by Actelion's misconduct. *Shkreli*, 581 F. Supp. 3d at 637 ("Generic drug companies need not undertake herculean efforts to overcome significant anticompetitive barriers specifically erected to prevent their entry into a market."); *Actavis*, 787 F.3d at 656 ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit." (quoting *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005))).

Second, this Court should reject Actelion's (third) attempt to graft a "prior course of dealing" element onto GEHA's claims. "The Supreme Court has never held that termination of a preexisting course of dealing is a necessary element of an antitrust claim."[89] Brand companies

[88] *See New York v. Actavis PLC*, 787 F.3d 638, 656 (2d Cir. 2015) ("generics need not be barred from all means of distribution if they are barred from the cost-efficient ones").

[89] *Mylan*, 2014 WL 12810322, at *6 (quotations, citations omitted); *Steward Health Care Sys., LLC v. BCBS of R.I.*, 311 F. Supp. 3d 468, 483 (D.R.I. 2018). Actelion claims that *Trinko*

typically have no prior reason to deal with generics.[90] A prior dealing requirement thus could in effect nullify Hatch-Waxman. To the extent prior dealing is considered, what matters is that Actelion had a decade's history of profitably selling Tracleer. It could have profitably sold to the generics, and its decision not to evidences its anticompetitive intent. *Aspen*, 472 U.S. at 611-12.

Lastly, Actelion claims immunity because Tracleer was protected by a patent. Br. 24–25. But there is no patent protection on branded pharmaceuticals being used to develop a generic version. The Hatch-Waxman Act enshrined a safe-harbor provision over such use. 35 U.S.C. § 271(e).[91] Indeed, Hatch-Waxman expressly encourages generics to file FDA applications *before* the brand's patents expire. *See Caraco*, 566 U.S. at 407. The Act cannot function if brands may withhold samples any time the product is patented. If accepted, Actelion's argument would erase the central achievements of Hatch-Waxman and the cost-saving generic industry it has fostered. In any event, here, the generics would have launched only *after* the patent expired.

In sum, Actelion claims that conduct which the Second Circuit Court of Appeals recently held to justify a *lifetime ban from the pharmaceutical industry* is, in fact, blameless—so much so that the only conclusion a reasonable juror could reach is to bless it. That argument is absurd. Foreclosing generics' access to essential samples enabled Actelion to delay competition, enrich itself, and force inflated prescription drug prices on patients and payers. It is unlawful.

"required" a prior course of dealing. Br. 24. Not so. *Trinko* noted that *Aspen* "found significance in the defendant's decision to cease participation in a cooperative venture," whereas in *Trinko*, "the defendant's prior conduct sheds no light upon [its] motivation." 540 U.S. at 409. Here, substantial evidence shows that Actelion's motive was to harm competition.

[90] Ex. 15, [redacted]; Ex. 32, (brands "do not ordinarily take orders from generic[s]").

[91] *Classen Immunotherapies, Inc. v. Shionogi, Inc.*, 993 F.Supp.2d 569, 576 (D. Md. 2014). Actelion's lone citation—*Applera Corp. v. MJ Rsch., Inc.*, 349 F. Supp. 2d 338 (D. Conn. 2004)—was not a pharmaceutical case and thus does not address the relevant regulatory context.

D. Reasonable jurors will find for GEHA on antitrust injury.

Defendants' antitrust injury arguments fail. First, they repeat the unsupported argument that the Tracleer REMS is what caused GEHA's injury. Br. 26–27. As explained, the Tracleer REMS did *not* require Actelion to erect the samples blockade. *Supra* § IV.B.1. What injured GEHA and the Class was "each time that Actelion sold Tracleer [] at monopoly prices after the patent's expiration." *Actelion*, 995 F.3d at 132. Actelion incredibly claims that "there is no dispute that Plaintiff's injury was caused by the restrictive nature of the FDA-mandated Tracleer REMS, not Actelion's conduct." Br. 27. This is hotly disputed. It is the very essence of the case. Because the REMS did not mandate the misconduct, Defendants' cited cases are irrelevant. For example, in *Canadian Import*, the plaintiffs sought to import drugs from Canada, but that was "prohibited by federal law." 470 F.3d 785, 791 (8th Cir. 2006). Here, no law required the samples blockade.[92] GEHA's injury flows directly from Actelion's anticompetitive scheme.[93]

Despite invoking a panoply of imagined "problems" with GEHA's causation case, Actelion's complaint boils down to one argument: that GEHA supposedly chose the wrong date for when generic companies would have acquired samples. Br. 29–30. This claim is false and flows from Defendants' misstatement of GEHA's claims. Specifically, Actelion wrongly claims that GEHA alleges only that generics were thwarted when Actelion directly "refus[ed] to supply samples of Tracleer in response to requests…." Br. 1, 26, 27, 30. In fact, GEHA alleges and the record shows the generics were thwarted earlier—months and in some cases years earlier—when

[92] *In re Wellbutrin* too is inapposite, because the generic company required a patent license plaintiffs did not show it could have obtained. 868 F.3d 132, 166-67 (3d. Cir. 2017). Here, the generics could have legally acquired samples earlier but for Actelion's conduct.

[93] That direct line of attribution contrasts this case with *Thompson Everett* (Br. 27), where the plaintiff could not establish that its damages flowed from conduct proscribed by the antitrust laws, 57 F.3d 1317, 1325 (4th Cir. 1995), or *Microbix* (Br. 25), where defendants' conduct was "not a substantial factor" contributing to the injury. 172 F.Supp.2d at 697–700.

Actelion's exclusionary contracts wrongfully prevented them from purchasing samples through the normal channels. It is that earlier date, as conservatively determined from the documents produced, when the generics would have obtained samples absent the anticompetitive conduct. *See* Ex. 5, Clark Rep. ¶ 273 (opining on a world in which "Actelion had not prevented generics from obtaining samples through the normal channels"); Ex. 7, Muzzio Rep. ¶¶ 23, 95.

Once Actelion's misdirection is corrected, its criticisms are easily dispensed with. Actelion points out that Zydus contacted Actelion in June 2010; but [redacted] Similarly as to [redacted], its [redacted] letter sent directly to Actelion followed many months of thwarted attempts to purchase Tracleer through the normal channels.[95] The same is true for [redacted].[96] As to [redacted], it is irrelevant whether they contacted Actelion directly; the record shows that [redacted] sought to purchase Tracleer by September 2008, and [redacted] by August 2011.[97] *Actelion does not actually dispute that the generics tried to buy Tracleer earlier through normal channels;* rather, it seeks to move the goalposts in an illogical way that will not persuade a jury, and cannot support summary judgment.

Even if the Court accepted Actelion's argument (it should not), that would not warrant summary judgment for two additional reasons. First, Defendants' brief addresses only one of the illustrative entry dates offered by Mr. Clark—December 28, 2015, *see* Br. 28–30—and ignores that Mr. Clark also opines that generics could have launched on December 28, 2016 or earlier.

[94] Ex. 28, 11/11/2009 Zydus Email.

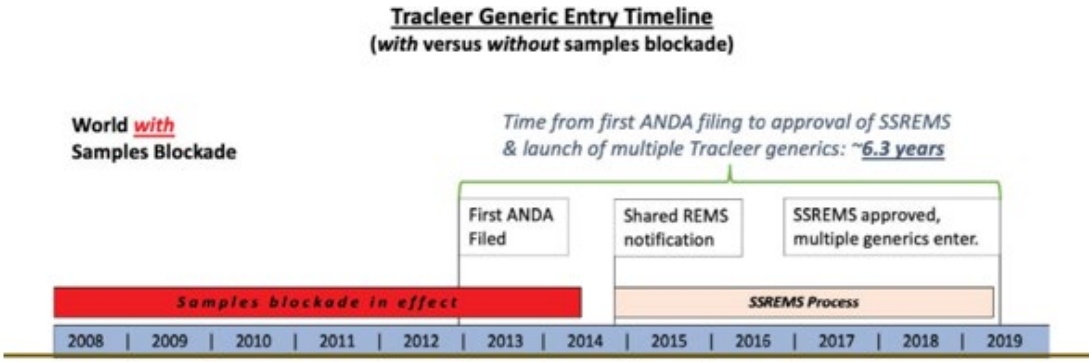
[95] [redacted]

[96] Ex. 5, Clark Rep. ¶¶ 111, 285, n.423.

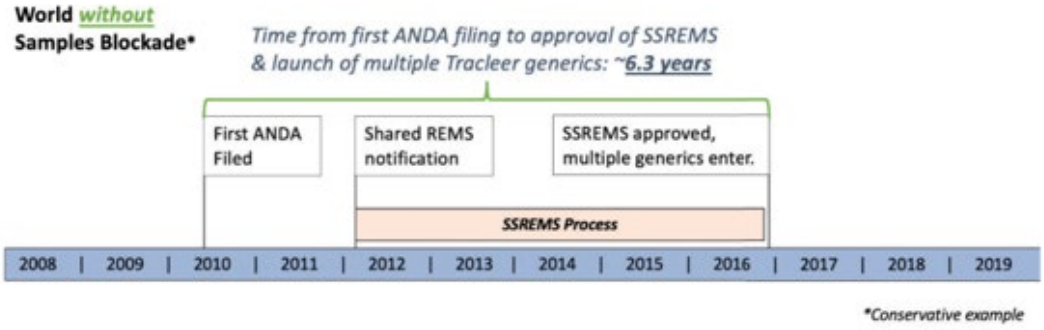
[97] [redacted].

Ex. 5, Clark Rep. ¶¶ 287–89. Actelion has not addressed nor justified dismissal of that alternative entry date. Second, Actelion does not argue there would have been no delay using *its* proposed dates. Even if a jury found that different dates were appropriate, Mr. Clark's model is flexible and can accommodate other launch dates under such a finding by the jury. *Id.* ¶ 290.

At bottom, GEHA's causation theory is simple. Actelion's years-long scheme to put a chokehold on the generic companies' necessary inputs delayed development and market entry:



Mr. Clark demonstrates that removing *only* Actelion's conduct and keeping the same time intervals between all other event results in earlier generic entry in 2016, rather than 2019:



See Ex. 50, Clark Rebuttal ¶ 116. The duration from ANDA filing to approval remains static (~6.3 years); the process just begins earlier. The delay is easily demonstrated, and reasonable jurors will find that Actelion's conduct caused injury to Plaintiff and the class in this way.

E. Actelion's spoliation precludes summary judgment.

The Court should deny summary judgment for the independent reason that Actelion spoliated relevant evidence. A party cannot destroy relevant evidence and then claim the record is wholly one-sided in its favor.[98] Here, the Court sanctioned Actelion after finding it destroyed *tens of thousands of documents* during the pendency of this case. ECF 216 at 20-23 ("[A] meaningful amount of relevant information was destroyed.") Actelion purged the files of multiple relevant company employees, including its President Shalom Jacobovitz (who was consulted on generics' requests for samples, *see* Ex. 62, at -833), and Michael Flinn (who Actelion admits had possessed relevant information regarding "requests for product samples," Ex. 70 at -805). The Court stated its intent to issue a jury instruction regarding Actelion's spoliation. ECF 216 at 22-23. It would be a profound injustice for Actelion to destroy highly relevant evidence and then obtain dismissal by arguing the record is one-sided in its favor.[99]

V. CONCLUSION

For the foregoing reasons, the motion for summary judgment should be denied.

Dated: March 21, 2024

Respectfully submitted,

/s/ Sharon K. Robertson
Sharon K. Robertson
Donna M. Evans
Aaron J. Marks

[98] *Schreane v. Beemon*, 575 F. App'x 486, 490 (5th Cir. 2014); *Byrnie v. Town of Cromwell, Bd. of Educ.*, 243 F.3d 93, 107 (2d Cir. 2001); *Butler v. Kroger Ltd. P'ship I*, 2020 WL 7483447, at *8-9 (E.D. Va. Nov. 30, 2020), *report and recommendation adopted* 2020 WL 7482186 (E.D. Va. Dec. 18, 2020) (denying summary judgment where defendant committed spoliation, because the destroyed material "may very well have provided significant evidence relevant to [the asserted] defenses, and supported [the plaintiff's] claim instead.")

[99] To be clear, the record is not one-sided in Actelion's favor: there are numerous disputes of material fact based on the record that exists. Spoliation is yet another reason to deny the motion.

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) on March 21, 2024.

Dated: March 21, 2024

/s/ Sharon K. Roberton
Sharon K. Robertson